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10/751,230	01/02/2004	Jinbo Xu	GLH 08-896943	1114
27667	7590	10/23/2007		
HAYES SOLOWAY P.C. 3450 E. SUNRISE DRIVE, SUITE 140 TUCSON, AZ 85718			EXAMINER BORIN, MICHAEL L	
			ART UNIT	PAPER NUMBER
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			10/23/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/751,230

**Applicant(s)**

XU ET AL.

**Examiner**

Michael Borin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04/26/2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-11, 13 and 15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11, 13 and 15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

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***DETAILED ACTION***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01/30/2007 and 04/26/2007 have been entered.

Note, that, per applicant request, this application has been the subject of 3-month suspension.

**Status of Claims**

Claims 1-11,13,15 are pending.

Rejections not reiterated from previous Office actions are hereby withdrawn. The following rejections constitute the complete set presently being applied to the instant application.

***Claim Rejections - 35 USC § 112, second paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11,13,15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 15 as amended, are directed to identify "the structure in the database", i.e., one structure in the database which fits the query protein sequence. However, the

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disclosure, the previous version of the claims, and the end of the current version of claim 1, address fitting of the query sequence to plurality of structures (set of structures) from the database. Please clarify via clearer claim language.

Claim 1: Further, now that the claim is directed to identifying "the structure in the database", i.e., one structure, it is unclear which template is addressed at the end of the claim.

***Claim Rejections - 35 USC § 112, first paragraph.***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-11,13,15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The rejection is applied for the following reasons:

A. Claims 1,15 introduce new matter as they recite "template comprising protein structures" (emphasis added). While specification uses closed "consisting" language with regard to "template"; e.g., p. 3, line 21, p. 4, line 3, p. 15, line 29, it does not teach

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a template comprised of protein structures as the latter term encompasses an assortment of non-liked structures pooled from a database.

Response to arguments

Applicant argues "The specification teaches a template. The specification also teaches protein structures. Thus.. the rejection is believed to be in error". The issue here is not the presence of proteins in the template, but the newly introduced "comprising" language.

B. Claims 1,15 introduce new matter as they recite that optimally aligned structure of template is identified as "the best fit". Although specification discloses how to perform method steps (Fig. 6, for example), it does not disclose that performing these steps results in identifying a "best fit".

Response to arguments

Applicant first discusses rejection concerning now deleted "template comprising..." language and argues "The specification teaches a template. The specification also teaches protein structures. Thus.. the rejection is believed to be in error". Then applicant states that for the same argument similarly applies to the instant rejection. The relevance of the argument ""The specification teaches a template. The specification also teaches protein structures" to the issue addressed in the instant rejection is not clear.

C. Claim 1: The claim as amended recites that "the structure of template that optimally aligns with the query sequence". Specification teaches that "one template is

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aligned to one sequence" (p. 6, lines 9,10, not that particular structures of template are aligned to the sequence.

Response to arguments

Applicant submits that comments addressed in section B, above, similarly apply to this rejection. The relevance of the argument ""The specification teaches a template. The specification also teaches protein structures" to the issue addressed in the instant rejection is not clear.

D. Claim 15: The claim as amended recites, that "the structure with minimum energy score being the final output". Specification, first, teaches alignment to a set of structures, not one structure. Second, specification does not disclose that the structure with minimum energy score is a final output.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Upon reconsideration of the claims the following rejection was deemed necessary, even in the presence of new matter language (which prompted withdrawal of the rejection in the preceding action):

3. Claims 1-11,13 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

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The instant claims are drawn to a computer process of aligning query protein sequence with protein structures. The method includes computational steps of selecting functions and constraints, and performing linear programming analysis. A statutory process must include a step of a physical transformation, or produce a useful, concrete, and tangible result. In the instant claims, there is no step of physical transformation, thus the Examiner must determine if the instant claims include a useful, concrete, and tangible result.

To be statutory, an invention must be directed to one of statutory categories enumerated in 35 USC § 101, or must produce a result which is useful, and tangible, and concrete. In determining if the instant claims are useful, tangible, and concrete, the Examiner must determine each standard individually. For a claim to be "useful," the claim must produce a result that is specific, substantial, and credible. For a claim to be "tangible," the claim must set forth a practical application of the invention that produces a real-world result. For a claim to be "concrete," the process must have a result that can be substantially repeatable or the process must substantially produce the same result again. Furthermore, the claim must recite a useful, tangible, and concrete result in the claim itself.

The instant claims do not include any tangible result. A tangible requirement requires that the claim must set forth a practical application of the computational steps to produce a real-world result. The last recited step of the method is "performing a linear programming analysis". This may take entirely within the confines of a computer or human mind without any communication to the outside world.

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To overcome the rejection, the claims may be amended to recite tangible output (e.g., displaying, etc.) or a subsequent physical transformation.

***Claim Rejections - 35 USC § 102 and 103.***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1,2,15 are rejected under 35 U.S.C. 102(b) as anticipated by Meller et al (Meller et al. Proteins: Structure, Function, and Genetics, 2001, Volume 45, Issue 3 , Pages 241 – 261).

The instant claims are drawn to method of aligning a query protein sequence with a template comprising a set of pre-selected protein structures in a database, comprising the steps of:

- selecting an energy function, said energy function being a linear combination of energy parameters, with weight factors as coefficients;
- establishing linear programming (LP) constraints for threading (or aligning) said query protein sequence with each structure in said set of pre-selected protein structures in a database;



- and performing a linear programming analysis based on a linear programming formulation including said energy function under said constraints,
- to optimally align said query protein with said template,
- the structure of the template that optimally aligns with the query protein sequence identified as the best fit.

Meller et al teach scoring method for sequence-to-structure alignments with parameters optimized by linear programming (LP). The method comprises steps of

- selecting an energy functions including energy parameters and weighting factors, determining values for weighting factors in said energy function (see pp. 242-244),
- using linear programming (LP) to identify constraints for threading. p. 243, right column through p. 244, left column, Table II, or p. 245, right column, or p. 248, left column last line.
- Performing linear programming on training sets of proteins (viewed as templates) - see, for example, p. 244, left column, pages 245-246.
- Performing threading to optimally align query protein. p. 251-255

#### Response to arguments

Applicant argues that, although Meller et al describe use of threading, they do not perform threading using linear programming. However, the instant claims only mention establishing LP constraints for threading (which Meller describes), not using LP for

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threading itself. The language "performing linear programming analysis" does not mean that threading itself is done using LP.

Further, the claims use open-ended language "comprising", and as such, may encompass any other steps, such as using dynamic programming addressed in the reference.

5. Claims 3-7,11,13 are rejected under 35 U.S.C. 103(a) as obvious over Meller et al in view of Akutsu et al. in view of Akutsu et al. (On the Approximation of Protein Threading. RECOMB, 1997, p. 3-8)

The reference of Meller et al is applied as above.

With respect to claims 3-7,11,13 if there are any differences between Applicant's claimed method and that of the prior art, the differences would be appear minor in nature. Although the prior art do not teach the various limitations of linear programming analysis and graph analysis, it would be conventional and within the skill of the art to select and/or determine such conditions as their selection for the intended purpose of obtaining successful protein threading algorithm is well known in the art; and the selection of appropriate parameters for linear programming is conventional and within the skill in the art to which this invention pertains. See Akutsu et al, for example.

#### Response to arguments

Applicant argues that Akutsu reference does not remedy the deficiency of Meller with regard to use of LP for threading. This issue is addressed above in discussing rejection under 35 U.S.C. 102(b).

6. Rejection of claim 12 under 35 U.S.C. 103(a) as obvious over Meller et al in view of Ding et al is withdrawn in view of cancellation of the claim.

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***Conclusion.***

7. No claims are allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571)272-0720 . The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael Borin, Ph.D.

Primary Examiner

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mlb